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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,889	02/21/2001	Earl R. Owen	12724-002001	6045

7590 09/30/2002  
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Suite 500  
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EXAMINER

CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/30/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/719,889

Applicant(s)

OWEN ET AL.

Examiner

Billy D Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because of the use of terminology/phraseology like "e.g.". Such reference to specific examples should be removed. Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite as it is not clear in the wording of the claim whether the recitation of "which are denatured" is a prophetic statement regarding when the denaturing will take place. It should be more concise in the claim whether the solder alone comprises a denatured protein or if the solder *will* comprise a denatured protein after administration and repair has begun.

Claims 1, 11, 17 and 19 are indefinite for the recitation of the term "substantially solid solder," wherein substantially solid is not clear regarding the malleability, consistency or durability.

Claims 6-7 are indefinite for lacking antecedent basis in claim 1 for the recitation of an adjuvant in claim 1.

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Claims 8-9 are indefinite for lacking antecedent basis in claim 1 for the recitation of "a material."

Claims 19-21 are indefinite for lacking antecedent basis in claim 11 for the recitation of a "dye."

Claims 23-25 are indefinite for lacking antecedent basis in claim 11 for the recitation of "shaping."

Claim 26 is indefinite for lacking antecedent basis in claim 11 for the recitation of "sterilizing."

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6-7, 11-14, 16-17 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Poppas, U.S. Patent No. 5,713,891. Poppas teaches the use of a denatured protein/dye solder with an adjuvant (i.e. albumin, indocyanine green and growth factors) for the repair of damaged biological tissues. Claims 1-2 require a denatured protein solder, see column 11, lines 6-9. Claim 3 requires the solder to be albumin, elastin, collagen or fibrinogen, see column 5, lines 3-7. Claims 4-5 require a dye, see column 5, lines 20-37. Claims 6-7 require an

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adjuvant for promoting rapid or more complete tissue healing, see column 5, lines 53-67 and column 6, lines 1-54. Claims 11-13 set forth method steps for making by forming solder, denaturing solder, and drying solder, see column 5, lines 1-67 and column 6 lines 1-67. Claims 16 requires exposing composition to a compound for denaturing, see column 11, lines 14-26. Claim 17 requires mixing of biomolecules with solvent to form composition, see column 5 lines 53-67 and column 6 lines 1-54. Claim 27 requires the methods of repairing tissue comprising applying solder and exposing to energy for time to allow for repair, see column 11, lines 6-35.

Claims 1-3, 8-9, 11-17, 22, 24-25 and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Sawyer *et al.* U.S. Patent No. 5,749,895. Sawyer *et al.* teach the use of a denatured protein patch solder, to be used with an additional material mesh for support and with a material for solder strength and further comprising the steps of denaturing, solidifying and administering the solder. Claims 1-2 require a denatured protein solder, see column 12, lines 22-36. Claims 8-9 require a material for strengthening the solder, see column 3 lines 26-30. Claims 11-17 require forming the solder (column 6, line 14 through column 9, line 48), denaturing the solder by thermal energy (column 8, lines 16-19) or by mixing a composition (column 8, lines 23-25), drying the solder (column 8 lines 31-32).

6. Claims 1-2 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer, U.S. Patent No. 5,156,613. Sawyer teaches the use of a protein solder by denaturing a collagen filler material with energy for the purpose of soldering biological tissues by forming the composition, denaturing the composition and drying the composition and by moistening the composition prior to welding. (column 4, lines 50-60, column 9, lines 46-50 and column 10, lines 24-28) (column 7 lines 32-33). Claims 1-2 require protein solder, see column 9, lines 27-30.

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Claims 27-28 require moistening solder prior applying, then applying the protein solder and exposing to energy for bonding, see column 9 lines 46-50 and lines 24-31.

### *Conclusion*

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
16 September 2002

  
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